4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-4629]

Survey Methodologies to Assess Risk Evaluation and Mitigation Strategies Goals That Relate to Knowledge; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Survey Methodologies to Assess REMS Goals That Relate to Knowledge; Draft Guidance For Industry." This draft guidance provides recommendations to industry on conducting risk evaluation and mitigation strategies (REMS) assessment surveys used to evaluate respondent knowledge of REMS-related information. Most applicants use surveys to evaluate patients' and healthcare providers' understanding of the serious risks associated with, and safe use of, their drugs to assess REMS knowledge goals. The draft guidance discusses general principles and recommendations related to conducting REMS assessment knowledge surveys, including study design, survey instrument development, survey data collection and processing, and data analysis.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-4629 for the "Survey Methodologies to Assess REMS Goals That Relate to Knowledge." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Brian Gordon, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2486, Silver Spring, MD 20993-0002, 301-796-3960, Brian.Gordon@fda.hhs.gov; Doris Auth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2480, Silver Spring, MD 20993-0002, 301-796-0487, Doris.Auth@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Survey Methodologies to Assess REMS Goals That Relate to Knowledge." The Food and Drug Administration Amendments Act of 2007 (FDAAA) created section 505-1 (21 U.S.C. 355-1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which authorizes FDA to require a REMS for certain drugs if FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh its risks.

REMS elements may include a medication guide, a patient package insert, and/or a communication plan. FDA may also require certain elements to assure safe use (ETASU) as part of a REMS. The ETASU can include, for example, requirements that health care providers who prescribe the drug have particular training or experience, that patients using the drug be monitored, or that the drug be dispensed to patients with evidence or other documentation of safe use conditions. Certain REMS with ETASU may also include an implementation system through which the sponsor is able to monitor and evaluate implementation of the ETASU and work to improve their implementation. All REMS for drugs approved under a new drug application or a biologics license application must include a timetable for submission of assessments of the REMS. The timetable for submission of assessments must be, at a minimum, an assessment by 18 months after the strategy is initially approved, an assessment by 3 years after the strategy is initially approved, and an assessment in the 7th year after the initial approval of the REMS. For additional information about REMS, see the draft guidance for industry "Format and Content of a REMS Document," (82 FR 47529, October 12, 2017) available at

https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm184128.pdf.

The FD&C Act requires applicants to conduct assessments to evaluate the effectiveness of REMS. The statute specifies that the assessment for REMS must include an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether one or more such goals or such elements should be modified (section 505-1(g)(3) of the FD&C Act). The statute does not specifically describe how this assessment should be conducted. Many REMS include a goal related to knowledge, such as to inform or educate patients and healthcare providers about the serious risks associated with and safe use of a drug. When knowledge goals are part of a REMS, the REMS assessment plan generally includes, as appropriate, an evaluation of patients' and healthcare providers' understanding of the serious risk(s) associated with, and safe use of, the drug.

The purpose of the REMS knowledge assessment is to evaluate the target populations' knowledge about the serious risk(s) and safe use of the drug. Most applicants use surveys to evaluate patients' and healthcare providers' understanding of the serious risk(s) associated with, and safe use of, their drugs to assess REMS knowledge goals.

This draft guidance, which describes best practices for the design, conduct, and data analyses of the results of REMS assessment knowledge surveys to evaluate patients' and healthcare providers' understanding of the serious risk(s) associated with, and safe use of, a drug, incorporates input obtained from the June 7, 2012, public workshop on "REMS Assessments: Social Science Methodologies to Assess Goals Related to Knowledge," and the comments submitted to the docket opened in association with the workshop (FDA-2012-N-0408).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on conducting risk evaluation and mitigation strategy assessment surveys used to assess respondent knowledge of REMS-related information. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Elsewhere in this issue of the *Federal Register*, FDA is announcing the availability of the draft guidance "REMS Assessment: Planning and Reporting." The assessment of burden hours included in the NOA for the draft guidance "REMS Assessment: Planning and Reporting" includes the burden for conducting knowledge surveys when conducted in support of a REMS Assessment.

III. Electronic Access

Persons with access to the internet may obtain the document at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or https://www.regulations.gov.

Dated: January 17, 2019.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2019-00749 Filed: 1/31/2019 8:45 am; Publication Date: 2/1/2019]